UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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MIQUEL CARIAS, VALERIE GENTILE, JANET RAMIREZ, MICHAEL PICONE, EVELYN FLECHA, ZENA MATOS, on behalf of KAILEI MATOS, a minor, JAIME NINO, and HALONA JAFFE, individually and on behalf all others similarly situated,

Plaintiffs,

- against -

MONSANTO COMPANY, a Delaware corporation; DOES 1-10, inclusive,

Defendants.

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Case No. 15 CV 3677

PLAINTIFF'S MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANT MONSANTO COMPANY'S MOTION TO DISMISS PLAINTIFFS' SECOND AMENDED COMPLAINT

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INTRODUCTION

Plaintiffs were diagnosed with a number of illnesses, including leukemia and Non-Hodgkin's Lymphoma, following years of exposure to Monsanto's Roundup. Monsanto seeks to dismiss the Plaintiffs' claims for false advertisement, failure to warn and actual injuries from exposure to Roundup by arguing, in the main, that they are barred by express preemption. Monsanto is legally and factually wrong.

First, the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7. U.S.C. § 136 *et seq.,* does not expressly preempt Plaintiffs' claims. The United States Supreme Court, in *Bates v. Dow Agrosciences LLC,* made clear that FIFRA's preemption reach is narrow, and a claim is preempted *only if* Monsanto can show that Plaintiffs' claims impose requirements "different from or in addition to" those imposed by federal law. 544 U.S. 431, 432 (2005).

Monsanto thus bears the heavy burden of proving that Plaintiffs' claims are preempted, yet it fails to even state how Plaintiffs' Complaint seeks to impose requirements other than those imposed by federal law. To the contrary, Plaintiffs' claims that Monsanto had a duty to warn of Roundup's carcinogenic and dangerous effects are parallel to FIFRA's misbranding requirement that products contain warnings sufficient to protect the health of those exposed. Monsanto did not identify a single requirement that Plaintiffs seek to impose that is greater than or inconsistent with what FIFRA already requires with respect to branding and labeling. Instead, Monsanto leaves the Court and Plaintiffs to speculate *what specific requirements* Plaintiffs seek that are different from or in addition to and are thus preempted.[1]

Monsanto further attempts to obfuscate the analysis by interchanging Environmental Protection Agency ("EPA") labeling decisions with requirements imposed by federal law, proposition blatantly at odds with the plain language of the federal statutes, congressional

[1] To survive pre-emption, the state-law requirement need not be phrased in the identical language as its corresponding FIFRA requirement. *Bates* 544 U.S. at 454. Moreover, minimal overbreadth can be remedied by proper jury instructions rather than dismissal of Plaintiffs' claims. *See, Astiana v. Hai Celestial Grp., Inc.,* 783 F.3d 753, 757-58 (9th Cir. 2015).

intent and Supreme Court precedent interpreting the statute. In fact, the United States Supreme Court considered and rejected this in its *Bates* decision. *Id.* at 447. Because Plaintiffs' failure to warn claims, as well as those for false advertising under New York's General Business Law §§ 349 and 350, do not seek to impose any requirements that are different from or in addition to those imposed by FIFRA, they are not preempted.

In fact, precedent already exists to establish the fact that Plaintiffs' claims for false advertising under New York's General Business Law §§ 349 and 350 are not preempted. As will be further detailed, *infra*, in 1996, the New York Attorney General filed a lawsuit against Monsanto, challenging its ***false and misleading advertising*** of Roundup products as "practically non-toxic" to mammals, birds and fish. As a result of the New York Attorney General's claims, Monsanto agreed to stop "publishing or broadcasting any advertisements [in New York] that represent, directly or by implication" that "its glyphosate-containing pesticide products or any component thereof are safe, non-toxic, harmless or free from risk."

Monsanto's motion fails for other reasons as well. Although styled as a motion to dismiss, ***Monsanto fails to limit its arguments to the pleadings and assuming the truth of the allegations as the law requires for dismissal motions***, instead spending pages upon pages laying out self-serving "fact based" rhetoric, much of which has nothing to do with Roundup, or its active ingredient glyphosate. Indeed, in an apparent attempt to malign the World Health Organization, Monsanto suggests, without support and against prevailing evidence, that somehow world hunger would increase if Roundup were not available for food production and other similar preposterous facts. Of course, not only do Plaintiffs contest those assertions, but, more importantly, they are irrelevant to their allegations against Monsanto. Thus, the Court should ignore the many extraneous statements Monsanto inserts in its motion as irrelevant to the issues and as improper for a motion to dismiss.

LEGAL STANDARD

"A Rule 12(b)(6) motion tests the legal sufficiency of a claim." *Rosal v. First Fed. Bank of California,* 671 F.Supp.2d 1111, 1119 (N.D.Cal. 2009). In considering a motion to dismiss,

allegations of material fact in the complaint are taken as true and construed in the light most favorable to the plaintiff." *Stoner v. Santa Clara Cty. Office of Educ.*, 502 F.3d 1116, 1120 (9th Cir. 2007). A district court should only grant a motion to dismiss when plaintiffs have not pleaded "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. .Corp. v. Twombly,* 55 U.S. 544, 547 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal,* 556 U.S. 662, 663 (2009).

It is well-established that "the motion [to dismiss] is not a procedure for resolving a contest between the parties about the facts or the substantive merits of the plaintiff's case." *Chavez v. Blue Sky Nat.Beverage Co.,* 340 F. App'x 359, 360 (9th Cir. 2009). Indeed, when reviewing a motion to dismiss, a court may "consider only allegations contained in the pleadings, exhibits attached to the complaint, and matters properly subject to judicial notice." *Akhtar v. Mesa,* 698 F.3d 1202, 1212 (9t Cir. 2012), *see also, Freeman v. Town of Hudson,* 714 F.3d 29, 36 (1st Cir. 2013) (judicial notice limited to documents or facts subject to Federal Rule of Evidence 201). Yet, despite this well established standard of review, Monsanto's motion relies on a number of documents outside the pleadings that are not matters of public record. These documents are improper for purposes of a F.R.C.P. 12(b)(6) motion, and the Court must exclude Monsanto's extraneous citations in its review of this motion. *See* Fed. R. Civ. P. 12(d).

Plaintiffs' allege that Monsanto's warnings, labels and/or public statements and marketing materials were patently inadequate to warn of glyphosate/Roundup's risks. These allegations must be accepted as true at the pleading stage. And the adequacy of Monsanto's warnings is ultimately a question for the jury.

ARGUMENT

PLAINTIFFS' CLAIMS DO NOT IMPOSE REQUIREMENTS IN ADDITION TO OR DIFFERENT FROM FIFRA.

Monsanto's express preemption argument fails because Plaintiffs' false advertising and failure to warn claims are parallel to FIFRA's misbranding provisions. Monsanto bears the

considerable burden of establishing express preemption applies and in this instance has failed to do so. *See, Cortina v. Goy Foods, Inc.,* 94 F.Supp.3d 1174, 1186 (S.D.Cal. 2015). The Court must start with the "presumption that Congress does not intend to supplant state law." *De Buono v. NYSA-ILA Med. & Clinical Servs.Fund, 520 U.S. 806, 814 (1997).* This presumption is heightened "where federal law is said to bar state action in fields of traditional state regulation." *New York State Conf. of Blue Cross & Blue Shld Plans v. Travrs. Ins. Co.,* 514 U.S. 645, 655 (1995). Because states have traditionally regulated the fields of health and safety, the heightened presumption against preemption applies to this case. *Id.* "[T]here is a presumption against supplanting 'the historic police powers of the States' by federal legislation 'unless that [is] the clear and manifest purpose of Congress.' " *Gordon v. Virtumundo, Inc.,* 575 F.3d 1040, 1060 (9th Cir.2009).

Monsanto can only prevail by establishing that FIFRA's preemption of Plaintiffs' claims is "the clear and manifest purpose of Congress." *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485 (1996); *see also, Gordon v. Virtumundo, Inc.,* 575 F.3d 1040, 1060 (9th Cir. 2009) (quoting *Medtronic,* 518 U.S. at 485, "the purpose of Congress is the ultimate touchstone in every preemption case."). Courts determine Congress' intent by analyzing the language of the statute and the overall statutory scheme. *Gordon,* 575 F.3d at 1060. Additionally, where the text of a preemption provision is open to more than one plausible reading, courts ordinarily "accept the reading that *disfavors pre-emption." Bates v. Dow Agrosciences LLC* 544 U.S. 431, 499 (2005) (emphasis added). "This presumption against preemption leads us to the principle that express preemption statutory provisions should be given narrow interpretation." *Gordon,* 575 F.3d at 1060. "The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption.' *Bates,* 544 U.S. at 449.

Moreover, this history emphasizes the importance of providing an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items. See, *Mortier*, 501 U.S., at 613 (stating that the 1972 amendments' goal was to "strengthen existing labeling requirements and ensure that these requirements were followed in practice"). Particularly given that Congress amended FIFRA to allow EPA to waive efficacy review of newly registered pesticides (and in the course of those amendments made technical changes to

§136v(b)), it seems unlikely that Congress considered a relatively obscure provision like §136v(b) to give pesticide manufacturers virtual immunity from certain forms of tort liability. Over enforcement of FIFRA's misbranding prohibition creates a risk of imposing unnecessary financial burdens on manufacturers; under-enforcement creates not only financial risks for consumers, but risks that affect their safety and the environment as well. *Bates*, *supra*.

"By encouraging plaintiffs to bring suit for injuries not previously recognized as traceable to pesticides such as [the pesticide there at issue], a state tort action of the kind under review may aid in the exposure of new dangers associated with pesticides. Successful actions of this sort may lead manufacturers to petition EPA to allow more detailed labelling of their products; alternatively, EPA itself may decide that revised labels are required in light of the new information that has been brought to its attention through common law suits. In addition, the specter of damage actions may provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement." *Ferebee,* 736 F.2d, at 1541—1542.

In comparison to other federal statutes, FIFRA's preemption provision is fairly narrow in scope. *See, e.g., Mills v. Giant of Maryland, LLC,* 441 F. Supp. 2d 104, 108 (D.D.C. 2006) aff d, 508 F.3d 11 (D.C. Cir. 2007) ("The scope of FDCA's preemption clause is much broader than FIFRA's, prohibiting 'any' requirements as opposed to merely requirements 'for labeling or packing. '"). *The Act only preempts state requirements for labeling or packaging that are "in addition to or different from" those imposed by FIFRA.* 7 U.S.C.A. §136v(b). The Court must determine whether Plaintiffs' claims are substantively equivalent to FIFRA's requirements, focusing on the "elements of the common-law duty at issue." *Bates,* 544 U.S. at 445.

Here, Plaintiffs' warnings and false advertising claims do not involve requirements that are in addition to or different from those imposed by FIFRA for a number of reasons.[2]

[2] In support of its argument, Monsanto cites two nonbinding and unpublished class action opinions from the Northern District of Indiana and the Northern District of Ohio. Both deal with the same flea and tick product, and both are distinguishable. In *Wilgus,* the Court found preemption because "throughout their Complaint, the Plaintiffs reference the inadequacy of the labeling," claiming the product was un-merchantable when used *in accordance with*

First, as the Supreme Court in *Bates* made clear, common law claims that "enforce a federal requirement '[do] not impose a requirement that is different from or in addition to, requirements under federal law.'" *Bates,* 544 U.S. at 448 (quoting *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 513 (1996) 513, 0'Connor, J., concurring in part and dissenting in part); *see also Stengel v. Medtronic, Inc.,* 704 F.3d 1224, 1228 (9th Cir. 2013), *cert.denied,* 134 S. Ct. 283 (2014) (holding that state law requirements that parallel federal requirements are not preempted).

Here, Plaintiffs' false advertisement and failure to warn claims parallel requirements imposed by FIFRA's misbranding prohibitions – which are independent of, but must be considered, in tandem with FIFRA's labeling requirements.

FIFRA prohibits the sale or distribution of any pesticide that is misbranded. 7 U.S.C. § 136j(a)(l)(E). It is a matter of black letter law that when an herbicide manufacturer misbrands it product, it has violated FIFRA and *EPA approval of the label is not a valid defense.* Accordingly, FIFRA imposes an *independent requirement* upon herbicide manufacturers not to misbrand their product. An herbicide is misbranded if:

> (A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;
>
> (F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment; [or]
>
> (G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment[.]

7 U.S.C. § 136(q)(l)(F)-(G).

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the label instructions and even quoted from the "defective' label as an element of their claims. See, *Wilgus v. Hartz Mountain Corp.,* 2013 WL 653707, at *5-6. In *Smith,* Plaintiffs went further and alleged that FIFRA mandated warning was insufficient and that warnings *in addition to the FIFRA* requirements were necessary. *Smith v. Hartz Mountain Corp.,* 201 WL 5451726, at *3. Plaintiffs herein make no such claims. Instead, Plaintiffs maintain that warning requirements exist *independent of EPA's* labeling decisions. Unlike the plaintiffs in *Wilgus* and *Smith,* Plaintiffs are asserting state claims that are parallel to the FIFRA requirements because they to do not add or differ from Monsanto's FIFRA requirements.

Thus, when an herbicide manufacturer fails to warn, and thus misbrands its product, it violates FIFRA. The EPA's approval of its label is not a valid defense. FIFRA imposes an *independent requirement* upon herbicide manufacturers not to misbrand their products. Plaintiffs make precisely that allegation (*e.g.*, Monsanto misbrands Roundup products as safe and it fails to provide adequate warnings of Roundup's and/or glyphosate's dangers).

Monsanto's argument fails to acknowledge that (1) FIFRA's labeling requirements are independent of its misbranding requirements and (2) that the two go hand in hand and must be considered in tandem. Indeed, Monsanto begs the Court to ignore FIFRA's misbranding provision by arguing that its misbranded warning is somehow consistent with FIFRA's labeling requirements and thus any warning plaintiff seeks is "in addition to" and preempted.

Monsanto essentially leverages its misguided argument to suggest one provision of FIFRA "preempts" the other. To the contrary, preemption based on inconsistent requirements must be viewed against all of the requirements found in FIFRA, including the misbranding provision which requires that Monsanto provide additional warnings. *See, Bates v. Dow Agrosciences LLC,* 544 U.S. 431 (2005).

Here, Monsanto fails to identify a single obligation which Plaintiffs' claims impose that is in addition to or different from FIFRA's requirements. Instead, Monsanto ignores FIFRA's specific preemption provision, instead making two broad assertions that fail to establish preemption under FIFRA: (1) that EPA approved the product label; and (2) that EPA essentially made a 'finding' that glyphosate is not carcinogenic.[3] Both assertions misstate the facts and law. Monsanto cannot rely on an incorrect reading of the applicable law to meet its

[3] Monsanto's argument that the EPA's classification that glyphosate is not carcinogenic is based solely on extraneous matters, and, therefore, should be disregarded by the Court for this dismissal motion. Fed. R. Civ. P. 12(d). Moreover, the EPA disclaimed it's 1991 Group E glyphosate classification by stating in its classification letter that "[i]t should be emphasized that designation of an agent in Group *E...should not be interpreted as a definite conclusion that the agent will not be a carcinogen under any circumstances"(Emphasis* added). Here, Monsanto is essentially requesting the Court to improperly take on the role of the jury and determine a critical scientific fact in its initial 12(b)(6) motion, while not giving the Court the full set of facts.

burden. More importantly, Monsanto ignores the parallel federal requirements found in the misbranding provisions. 7 U.S.C. § 136j(a)(l)(E).

Roundup did not contain the necessary warnings under 7 U.S.C. § 136j(a)(l)(E), which, if complied with, would have been adequate to protect the health of those exposed to Roundup. *See, Carlin v. Superior Court,* 13 Cal. 4th 1104, 1112 (1996) (strict liability requires plaintiff to prove that defendant did not adequately warn of a risk that was known or knowable in light of generally recognized and prevailing best scientific and medical knowledge available at time of manufacture and distribution). Warning against Roundup's carcinogenic and dangerous effects is *parallel to* FIFRA's misbranding requirement that products contain warnings sufficient to protect the health of those exposed.

FIFRA already requires that a product label identify hazards to humans and domestic animals: "When data or other information show that an acute hazard may exist to humans or domestic animals, the label must bear precautionary statements describing the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect." 40 CFR § 156.70. Because Monsanto has not identified a single labeling or packaging requirement that is in addition to or different from those imposed by all of FIFRA's requirements (including those imposed under misbranding), Monsanto has failed to carry its considerable burden of establishing express preemption. *Astiana v. Hain Celestia Grp., Inc.,* 783 F.3d 753, 757-58 (9th Cir. 2015).

Additionally, Monsanto's contention that the EPA's approval[4] of the label preempts Plaintiffs' false advertising and failure to warn claims is at odds with the plain language of FIFRA. Specifically, this argument ignores Section 136a(f)(2), which states, in relevant part, that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter." Therefore, an herbicide can be registered but still violate FIFRA

[4] Monsanto's description of the EPA's "findings" (that glyphosate is not carcinogenic) as "consistent" and "repeated" is disingenuous, at best. Although the EPA *classified* glyphosate to Group E (non-carcinogen for humans) over one member's refusal to sign, the EPA initially classified glyphosate in 1985 as a Group C possible carcinogen. Monsanto's brief is misleading insofar as it omits the earlier finding.

by, among other things, failing to provide adequate warnings. 7 U.S.C. §§ 136j(a)(l)(E), (f)(2); *Bates,* 544 U.S. at 44 ("Because it is unlawful under the statute to sell a pesticide that is registered but nevertheless misbranded, manufacturers have a continuing obligation to adhere to FIFRA's labeling requirements."). Accepting Monsanto's wrong interpretation of section 136v(b) - namely, that the section "preempts any statutory or common-law rule that would impose a warning requirement that diverges from EPA's labeling decisions under FIFRA" -- renders Section136a(f)(2) meaningless.

Because an herbicide can be registered with an approved label and nonetheless still be misbranded, **FIFRA's plain language makes clear that warning requirements exist independent of EPA labeling decisions.**[5] If Congress wanted to make EPA's labeling decisions conclusory, Congress could have structured 136v(b) to forbid "any requirements for labeling or packaging that require a different label than that approved by the EPA." Congress has taken no such action. Instead, Congress added the language "in addition to or different from" as evidence of its intent that not all state court failure to warn claims are preempted.

Thus, a common law claim that parallels FIFRA's labeling and misbranding requirements does not impose different or additional requirements and is therefore not preempted. *See Bates,* 544 U.S. at 442 ("Nothing in the text of FIFRA would prevent a State from making the violation of a federal labeling or packaging requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate federal law. *The imposition of state sanctions for violating state rules that merely duplicate federal requirement is equally consistent with the text of § 136v.*") (Emphasis added).

Said another way, the imposition of state sanctions for violating state rules that merely duplicate federal requirements is equally consistent with the text of § 136v. *Bates,* 544 U.S. at 442. The tautological result of equating EPA "decisions" to "requirements" would frustrate the

[5] For instance, warnings different than those of EPA are often placed on a variety of products under California's "Prop 65" legislation. Recently, a notice of proposed rule-making has been written which will soon require Monsanto to place a Prop 65 warning on Roundup that Roundup is "known to the state of California to cause cancer." See, http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/090415LCset27.html

statute and render meaningless sections 136j(a)(l)(E) and 136a(f)(2). Accordingly, this Court should not adopt such a reading.

Monsanto's misreading and attempt to narrow *Bates* distorts the meaning of §136v(b) itself. Notably, Monsanto argues that 136v(b) preempts any statutory or common law rule that would impose a warning requirement that diverges from EPA's labeling decision." This interpretation eliminates all meaning from the latter part of 136v(b) ("in addition to or different from"). Had Congress intended 136v(b) to preempt *any* labeling requirement, the statute would have been written that "[s]uch state shall not impose or continue in effect any requirements for labeling or packaging.' This amputated version of §136v(b) would no doubt have clearly and succinctly commanded the pre-emption of *all* state requirements concerning labeling. That Congress added the remainder of the provision is evidence of its intent to draw a distinction between state labeling requirements that are pre-empted and those that are not.

The Court should adopt the reading disfavoring preemption. *Bates,* 544 U.S. at 499. Monsanto' expansive reading is contradicted by established precedent holding that parallel requirements are not in addition to or different from their federal counterparts. *Stengel v. Medtronic, Inc.,* 704 F.3d 1224, 1231 (9th Cir. 2013), *cert. denied,* 134 S. Ct. 283 (2014).

Even a showing that Plaintiffs' claims impose requirements that extend FIFRA requirements will not preclude Plaintiffs from meeting the pleading standard. "In undertaking a preemption analysis at the pleadings stage of a case, a court should bear in mind the concept of equivalence. To survive pre-emption, the state-law requirement need not be phrased in the identical language as its corresponding FIFRA requirement." *Bates* 544 U.S. at 454. Moreover, minimal overbreadth can be remedied by proper jury instructions rather than dismissal of Plaintiffs' claims. *See, Astiana v. Hain Celestial Grp., Inc.,* 783 F.3d 753, 757-58 (9th Cir. 2015) ("To the extent state law might be construed more broadly than federal law, the solution is not to prohibit state law suit altogether, but to 'instruct the jury on the relevant [federal] standards, as well as any regulations that add content to those standards."). Thus, even if some claims minimally extend FIFRA requirements, Plaintiffs' warning and false advertising claims are not barred as a matter of law where additional requirements may be cured through jury instruction.

EPA'S GLYPHOSATE CLASSIFICATIONS ARE IRRELEVANT

Monsanto's reliance upon factual assertions about EPA classifications regarding glyphosate's purported "safety" are irrelevant and improper, as the EPA itself has stated that it has made no determination of carcinogenicity and/or safety with regard to Roundup.[6] Classifications by the EPA do not constitute clear and manifest statements of Congressional intent that herbicides cannot be challenged as unsafe under state tort law. *Arias v. Dyncorp,* 517 F. Supp. 2d 221, 229 (D.D.C. 2007); *Ferebee v. Chevron Chem. Co.,* 736 F.2d 1529, 1539-40 (D.C.Cir.1984) (finding that a federal agency's determination that a product was safe for distribution under federal law and did not "pose an unreasonable risk to the normal user," did not preempt state tort claims challenging labeling).[7]

Rather, that is a question for the fact finder to determine, especially true after Monsanto was prohibited from stating and/or advertising that Roundup was "safe" after a lawsuit was brought by the New York State Attorney General. *See,* **Exhibit "A"**, annexed hereto.

Moreover, it is curious to note that, with respect to Roundup's purported "safety", Monsanto makes no mention of the state of California's recent "Prop 65" legislation. *See*, Footnote 5, *supra*. Specifically, a notice of proposed rule-making has been written which will soon require Monsanto to place a Prop 65 warning on Roundup that it is "known to the state of California to cause cancer." Seemingly, Monsanto's position that Roundup "does not affect people, just plants", is "safe" and "non-carcinogenic", etc., is strongly at odds with the state of California, which intends to affix a Prop 65 label that states that Roundup "causes cancer" in people.

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[6] Furthermore, such statements are not accurate as the EPA included specific disclaimers regarding its Group E classification of glyphosate. *See,* Footnotes 3 and 4, *supra.*

[7] The majority in *Bates* recognized that FIFRA contemplates that labels will evolve as new and relevant information surfaces. *"Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA.* Unlike the cigarette labeling law at issue in *Cipollone,* which prescribed certain immutable warning statements, FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings." *Bates,* 544 U.S. at 451 (emphasis added).

NEW YORK'S GENERAL BUSINESS LAW §§ 349 AND 350 ARE CONSISTENT WITH, AND FULLY EQUIVALENT TO, FIFRA'S MISBRANDING PROVISIONS

Section 349 (a) of the General Business Law encompasses deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in New York State. Section 349 governs consumer-oriented conduct and, on its face, applies to virtually all economic activity. *Karlin v. IVF Am.*, 93 N.Y.2d 282, 290, 690 N.Y.S.2d 495, 712 N.E.2d 662. Generally, claims under the statute are available to an individual consumer who falls victim to misrepresentations made by a seller of consumer goods through false or misleading advertising. *Genesco Entertainment v. Koch*, 593 F.Supp. 743, 751 (S.D.N.Y. 1984).

To state a claim under the statute, a plaintiff must allege that the defendant has engaged "in an act or practice that is deceptive or *misleading in a material way* and that plaintiff has been injured by reason thereof." *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 85 N.Y.2d 20, 25, 623 N.Y.S.2d 529, 647 N.E.2d 741 (emphasis added).

Section 350 of the General Business Law provides that "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state is hereby declared unlawful."

Section 350-a of the General Business Law provides "[t]he term 'false advertising' means advertising, *including labeling*, of a commodity, or of the kind, character terms or conditions of any employment opportunity if such advertising is *misleading in a material respect*" (emphasis added).

Conversely, the misbranding provision of the federal statute at issue requires that a pesticide label not contain statements that are "false or misleading *in any particular*." 7 U.S.C. § 136(q)(1)(A) (emphasis added).

In undertaking a pre-emption analysis at the pleadings stage of a case, a court should bear in mind the concept of equivalence. *Bates, supra.* To survive pre-emption, the state-law requirement need not be phrased in the *identical* language as its corresponding FIFRA requirement; indeed, it would be surprising if a common-law requirement used the same

phraseology as FIFRA. If a case proceeds to trial, the court's jury instructions must ensure that nominally equivalent labeling requirements are ***genuinely*** equivalent. *Id.* (emphasis added). *See also, DJ Coleman, Inc. v. Nufarm Americas, Inc.*, 693 F. Supp. 2d 1055 (D.N.D. 2010) (holding that state law ***fraudulent advertising claims*** were not preempted if state law was "equivalent to, and fully consistent with, FIFRA's misbranding provisions").

In *DJ Coleman, Inc., supra*, the plaintiff's fraudulent advertising claims were based on written[1] representations on the defendant's label that its product was safe for use on sunflowers. Plaintiff's claims for fraudulent advertising were brought under Section 51-15-02 of the North Dakota Century Code which describes the unlawful advertising practices governed under North Dakota's Consumer Fraud Act. The Defendant alleged, in turn, that plaintiff's claims were preempted by FIFRA.

The court, in undertaking its preemption analysis, compared the language of Section 51-15-02 of the North Dakota Century Code with the misbranding provision of FIFRA, 7 U.S.C. § 136(q)(1)(A), which simply provides that a pesticide label should not contain statements that are "false or misleading in any particular."

Section 51-15-02 of the North Dakota Century Code provides:

> *51-15-02. Unlawful practices — Fraud — Misrepresentation. The act, use, or employment by any person of any deceptive act or practice, fraud, false pretense, false promise, or misrepresentation, with the intent that others rely thereon in connection with the sale or advertisement of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is declared to be an unlawful practice.*

In finding that FIFRA pre-empted plaintiff's claims under North Dakota's Consumer Fraud Act, the court made it plain that the element of falsity or misrepresentation was broader under N.D.C.C. ch. 51-15 than under FIFRA's curt obligation that labels not contain false or misleading statements. Therefore, the court held that N.D.C.C. § 51-15-02 was not genuinely

equivalent to FIFRA's obligation under 7 U.S.C. § 136(q)(1)(A).

In undertaking the same analysis herein, however, it is abundantly clear that this court should arrive at a sharply different conclusion than the court in *DJ Coleman, Inc., supra.*

As mentioned previously, to state a claim under Section 349 of New York's General Business Law, a plaintiff must allege that the defendant has engaged "in an act or practice that is deceptive or *misleading in a material way* and that plaintiff has been injured by reason thereof." See, *Oswego, supra.*

Section 350-a of New York's General Business Law provides "[t]he term 'false advertising' means advertising, *including labeling*, of a commodity, or of the kind, character terms or conditions of any employment opportunity if such advertising is *misleading in a material respect*" (emphasis added).

FIFRA's misbranding provision, 7 U.S.C. § 136(q)(1)(A), provides that a pesticide label should not contain statements that are "false or misleading in any particular."

Clearly, when comparing the language of §§ 349 & 350 with FIFRA's misbranding provision, it is apparent that the element of falsity or misrepresentation is ***not*** broader under §§ 349 & 350 than under FIFRA's obligation that labels not contain false or misleading statements.

Instead, it is abundantly plain that §§ 349 & 350, which requires labels to not be "*misleading in a material way/respect*" is genuinely equivalent to FIFRA's requirement that labels not be "*false or misleading in any particular*."

More pointedly, in what possible respect is there a lack of general equivalency between the terminology "misleading in a material respect" and "misleading in any particular"?

PRECEDENT EXISTS TO ESTABLISH THAT PLAINTIFFS' CLAIMS FOR FALSE ADVERTISEMENT UNDER NEW YORK'S GENERAL BUSINESS LAW § 350 ARE NOT PREEMPTED

In 1996, the New York Attorney General ("NYAG") filed a lawsuit against Monsanto pursuant to ***New York General Business Law § 350*** based on its ***false and misleading advertising*** of Roundup products.

Specifically, the lawsuit challenged Monsanto's general representations that its spray-on glyphosate-based herbicides, including Roundup, were "safer than table salt" and "practically non-toxic" to mammals, birds, and fish. Among the representations the NYAG found deceptive and misleading about the human and environmental safety of glyphosate and/or Roundup were the following:

a) "Remember that environmentally friendly Roundup herbicide is biodegradable. It won't build up in the soil so you can use Roundup with confidence along customers' driveways, sidewalks and fences ..."

b) "And remember that Roundup is biodegradable and won't build up in the soil. That will give you the environmental confidence you need to use Roundup everywhere you've got a weed, brush, edging or trimming problem."

c) "Roundup biodegrades into naturally occurring elements."

d) "Remember that versatile Roundup herbicide stays where you put it. That means there's no washing or leaching to harm customers' shrubs or other desirable vegetation."

e) "This non-residual herbicide will not wash or leach in the soil. It ... stays where you apply it."

f) "You can apply Accord with 'confidence because it will stay where you put it' it bonds tightly to soil particles, preventing leaching. Then, soon after application, soil microorganisms biodegrade Accord into natural products."

g) Glyphosate is less toxic to rats than table salt following acute oral ingestion.

h) "Glyphosate's safety margin is much greater than required. It has over a 1,000-fold safety margin in food and over a 700-fold safety margin for workers who manufacture it or use it."

i) "You can feel good about using herbicides by Monsanto. They carry a toxicity category rating of 'practically non-toxic' as it pertains to mammals, birds and fish."

j) "Roundup can be used where kids and pets will play and breaks down into natural material." This ad depicts a person with his head in the ground and a pet dog standing in an area which has been treated with Roundup.

The Attorney General maintained that Monsanto's claims were not accurate and contradicted several statements ***required on the EPA-approved label for Roundup***. The Attorney General thus charged that Monsanto's advertising claims constituted a violation of FIFRA, 7 U.S.C. § 136j(a)(l)(B). The Attorney General further charged that Monsanto had engaged in false and misleading advertising in violation of General Business Law § 350.

On November 19, 1996, Monsanto entered into an Assurance of Discontinuance with NYAG, in which Monsanto agreed, among other things, "to cease and desist from publishing or broadcasting any advertisements [in New York] that represent, directly or by implication" that:

a) its glyphosate-containing pesticide products or any component thereof are safe, non-toxic, harmless or free from risk;

b) its glyphosate-containing pesticide products or any component thereof manufactured, formulated, distributed or sold by Monsanto are biodegradable its glyphosate-containing pesticide products or any component thereof stay where they are applied under all circumstances and will not move through the environment by any means;

c) its glyphosate-containing pesticide products or any component thereof are "good" for the environment or are "known for their environmental characteristics.";

d) its glyphosate-containing pesticide products or any component thereof are safer or less toxic than common consumer products other than herbicides;

e) its glyphosate-containing products or any component thereof might be classified as "practically non-toxic."

Monsanto did not alter its advertising in the same manner in any state other than New York, and on information and belief it still has not done so today.

It is thus readily apparent that precedent exists to clearly establish that Plaintiffs' claims herein under New York's General Business Law for false advertising are not preempted by FIFRA. Otherwise, why would Monsanto have entered into the Assurance of Discontinuance with the NYAG when like claims were made against it in 1996? Why were the NYAG's claims not preempted then? Or is it Monsanto's position that the claims should be preempted now because they have been filed on behalf of Plaintiffs by the diminutive law office of Gabrielli Levitt LLP as opposed to the powerful NYAG?

MONSANTO'S RELIANCE ON *MIZRAIE V. MONSANTO CO.* IS MISPLACED

Monsanto's reliance on the recent decision in *Mizraie v. Monsanto Co.*, 2016 U.S. Dist. LEXIS 3816, is grossly misplaced.

Mizraie involved the issue of whether the 13- word slogan on the Roundup label at issue herein, *i.e., "[g]lyphosate targets and enzyme found in plants but not in people or pets,"* violated ***California's*** False Advertising Law, Cal. Bus. & Prof. Code Section 17500.

Mizraie did ***not*** involve to ***any degree whatsoever*** an analysis of whether §§ 349 & 350 of ***New York's*** General Business Law is genuinely equivalent to FIFRA's misbranding requirement.

The *Mizraie* court did not make any attempt to compare the language of New York General Business Law §§ 349 & 350 with FIFRA's misbranding provision in order to determine whether the element of falsity or misrepresentation is broader under §§ 349 & 350 than under FIFRA's obligation that labels not contain false or misleading statements.

Moreover, it is respectfully submitted that the *Mizraie* court adopted an incorrect and outdated (pre-*Bates, supra*) method of analysis in order to arrive at its conclusion.

In particular, in holding that plaintiffs claims under California's False Advertising Law were preempted by FIFRA, the Court states:

> "There can be no dispute that Plaintiffs seek to impose a labeling requirement different or in addition to that required under FIFRA, as the Roundup label to which Plaintiffs object, and which Plaintiffs seek to alter, *was approved by the Environmental Protection Agency* in 2008 . . . [h]ere, because the injunction Plaintiffs seek under Section 17500 *would require Defendant to alter its label*, Plaintiffs request falls squarely within the definition of 'requirements'" (emphasis added).

The *Mizraie* court's "effects-based test" analysis was specifically struck down by the court in *Bates*, *supra*.

Specifically, the *Bates* court highlighted that, in holding for the Defendant, Dow, the lower court had reasoned that a finding of liability on plaintiff's claims would induce the defendant to "alter [its] label." As per the court in *Bates*, however:

> This effects-based test finds no support in the text of §136v(b), which speaks only of "requirements." A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an examination of the elements of the common-law duty at issue; *it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action.*
>
> Moreover, the inducement test is not entirely consistent with §136v(a), which confirms the State's broad authority to regulate the sale and use of pesticides. Under §136v(a), a state agency may ban the sale of a pesticide if it finds, for instance, that one of the pesticide's label-approved uses is unsafe. This ban might well induce the manufacturer to change its label to warn against this questioned use. Under the inducement test, however, such a restriction would anomalously qualify as a "labeling" requirement (emphasis added). *Id.*

Further, the *Mizraie* court's argument that the plaintiffs therein sought to impose a labeling requirement different or in addition to that required under FIFRA because the Roundup label "was approved by the EPA" was considered and rejected by the United States Supreme Court in *Bates*. *Id.* at 447.

The *Mizraie* court's attempt to obfuscate the proper analysis of FIFRA preemption by interchanging EPA labeling decisions with requirements imposed by federal law is a position blatantly at odds with the plain language of the federal statutes, congressional intent

and Supreme Court precedent interpreting the statute.

It is a matter of black letter law that when an herbicide manufacturer misbrands it product, it has violated FIFRA and ***EPA approval of the label is not a valid defense.***

Thus, when an herbicide manufacturer misbrands its product, it violates FIFRA. The EPA's approval of its label is not a valid defense. FIFRA imposes an *independent requirement* upon herbicide manufacturers not to misbrand their products.

If Congress wanted to make EPA's labeling decisions conclusory, Congress could have structured 136v(b) to forbid "any requirements for labeling or packaging that require a different label than that approved by the EPA." Congress has taken no such action. Instead, Congress added the language "in addition to or different from" as evidence of its intent that not all state court claims are preempted. Thus, a common law claim that parallels FIFRA's labeling and misbranding requirements does not impose different or additional requirements and is therefore not preempted. *See Bates,* 544 U.S. at 442 ("Nothing in the text of FIFRA would prevent a State from making the violation of a federal labeling or packaging requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate federal law. *The imposition of state sanctions for violating state rules that merely duplicate federal requirement is equally consistent with the text of § 136v.*") (Emphasis added).

The tautological result of equating EPA "decisions" to "requirements" would frustrate the statute and render meaningless sections 136j(a)(l)(E) and 136a(f)(2).

The *Mizraie* court's misreading and attempt to narrow *Bates* distorts the meaning of §136v(b) itself. Notably, the *Mizraie* court seemingly holds that 136v(b) preempts any statutory or common law rule that would impose a warning requirement that diverges from EPA's labeling decision. This interpretation eliminates all meaning from the latter part of 136v(b) ("in addition to or different from"). Had Congress intended 136v(b) to preempt *any* labeling requirement, the statute would have been written that "[s]uch state shall not impose or continue in effect any requirements for labeling or packaging." *Bates,* 544 U.S. at 499.

Congress specifically determined that compliance with the registration requirements set forth by the Administrator of the Environmental Protection Agency would ***not*** conclusively establish compliance with FIFRA's labeling requirements. 7 U.S.C. Sec. 136a(f)(2). To the contrary, if no cancellation proceedings are in effect, registration of a pesticide only constitutes "prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions" outlined in the Act.

By thus declining to determine whether the claims raised by the plaintiffs in *Mizraie* are consistent with FIFRA's broad labeling requirements, the *Mizraie* court failed to complete the preemption analysis mandated by *Bates*. In so doing, the the *Mizraie* court has improperly allowed FIFRA to trample upon state law which is arguably consistent with the requirements set forth within the Act. Our federalism dictates that we refrain from extending federal power into state territory unless Congress intended such an extension. It is thus respectfully submitted that the *Mizraie* court has paid short shrift to the ideals of federalism and its opinion should be disregarded herein for the foregoing reasons.

THE PORTION OF THE LABEL AT ISSUE DOES NOT FALL WITHIN THE STATUTORY SAFE HARBOR OF GBL SECTIONS 349 AND 350

Monsanto's attempt to seek protection under the safe harbor provisions of the New York GBL also fails. Section 349(d) provides that, in a deceptive practice action, "it shall be a complete defense that the act or practice is . . . subject to and complies with the rules and regulations of, and the statutes administered by, the federal trade commission [sic] or any official department, division, commission or agency of the United States." Likewise, § 350-d provides that, in any false advertising action, "it shall be a complete defense that the advertisement is subject to and complies with the rules and regulations of, and the statutes administered by the Federal Trade Commission or any official department, division, commission or agency of the state of New York." "Courts have construed § 350-d to be congruent with § 349(d) and also to cover regulations promulgated by federal agencies other than the FTC." *Marcus v. AT&T Corp.*, 938 F.Supp. 1158, 1173 (S.D.N.Y. 1996) (citing *Am. Home Prods. Corp. v. Johnson & Johnson,* 672 F.Supp. 135, 144 (S.D.N.Y.1987) and *Mendelson v. Trans World Airlines, Inc.*, 120 Misc.2d 423 (Sup. Ct. Queens County 1983)).

Herein, it is not clear that the portion of Monsanto's label at issue, i.e., the 13- word slogan which states that *"[g]lyphosate targets and enzyme found in plants but not in people or pets*," "complies with" the rules and regulations of any agency of the United States or the State of New York. *See, Am. Home Products Corp.*, 672 F. Supp. at 144-45 (S.D.N.Y. 1987) (implying that the safe harbor provisions apply only "where the FDA has explicitly endorsed the particular facet of the labeling which is claimed to be inadequate").

Moreover, and for the reasons set forth above, that the EPA, et al., do not specifically forbid the labeling at issue here does not necessarily afford Monsanto the safe harbors' protections. *See, Sclafani v. Barilla Am., Inc.*, 19 A.D.3d 577, 577 (2005) ("`[C]ompliance with regulations does not immunize misconduct outside the regulatory scope.'") (quoting *Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris, Inc.*, 133 F.Supp.2d 162, 175 (E.D.N.Y. 2001)).

Accordingly, inasmuch as there remains an issue as to whether:

(1) the portion of Monsanto's label at issue, i.e., the 13- word slogan which states that *"[g]lyphosate targets and enzyme found in plants but not in people or pets*," violates 7 U.S.C. § 136(q)(1)(A); and

(2) Monsanto has misbranded Roundup in violation of 7 U.S.C. § 136(q)(1)(F) and 7 U.S.C. § 136(q)(1)(G),

Monsanto should not be afforded the safe harbors' protections at this time.

PLAINTIFFS' CLAIMS UNDER GBL SECTIONS 349 AND 350 ARE PROPERLY PLEAD

Monsanto waxes eloquent about how the Plaintiffs herein supposedly fail to satisfy their burden to allege a false or misleading statement by relying upon the purported scientific "fact" that glyphosate targets the "shikimate enzyme." Monsanto, however, offers no scientific "facts" in support of its theory surrounding the "shikimate enzyme" and engages in linguistic gymnastics in an attempt to confuse the Court as Plaintiffs' straightforward science-based theory regarding

glyphosate's effect on humans.

Notwithstanding the fact that Monsanto's argument in this regard is improper for a pre-Answer motion to dismiss, it is respectfully submitted that the challenged slogan, *"[g]lyphosate targets an enzyme found in plants, but not in people or pets,"* is most certainly false.

As evidence, Plaintiffs offer a declaration previously filed in the *Mizraie* matter, *supra*, annexed as **Exhibit "B"**, from world-renowned scientists and doctors who have researched and published on glyphosate issues. These veteran scientists testify that glyphosate affects enzymes "found in" people. These veteran scientists are unimpeachable and, at a minimum, their declaration creates a question of fact to be determined.

In addition, Monsanto mistakenly contends that Plaintiffs' personal injury damages are not recoverable under §§ 349 & 350 of New York's General Business Law because "[t]hese sections make no mention whatsoever of personal injuries." Nothing could be further from the truth.

Inasmuch as Monsanto has conveniently failed to cite the complete relevant language of §§ 349 & 350, the undersigned will note herein that § 349(h) provides:

> h) In addition to the right of action granted to the attorney general pursuant to this section, any person who has been ***injured*** by reason of any violation of this section may bring an action in his own name to enjoin such unlawful act or practice, an action to recover his ***actual damages*** or fifty dollars, whichever is greater, or both such actions (emphasis added).

Section 350-e(3) provides:

> 3. Any person who has been injured by reason of any violation of section three hundred fifty or three hundred fifty-a of this article may bring an action in his or her own name to enjoin such unlawful act or practice, an action to recover his or her ***actual damages*** or five hundred dollars, whichever is greater, or both such actions. The court may, in its discretion, increase the award of damages to an amount not to exceed three times the actual damages, up to ten thousand dollars, if the court finds that the defendant willfully or knowingly violated this section. The court may award reasonable attorney's fees to a prevailing plaintiff (emphasis added)

In *Small v Lorillard Tobacco Company Inc.*, 94 N.Y.2d 43 (1999), the plaintiffs brought a claim under Section 349 (a) of the General Business Law alleging that defendant, a tobacco company, deceived them about the addictive properties of cigarettes and fraudulently induced them to purchase cigarettes.

Plaintiffs argued that the Appellate Division incorrectly held that they had to prove that they were addicted to nicotine in order to allege a cognizable injury and harm, as contemplated and prescribed by the statute. According to the plaintiffs, addiction was not the injury; rather, plaintiffs asserted that defendants' deception prevented them from making free and informed choices as consumers. Plaintiffs posited, in essence, that consumers who buy a product that they would not have purchased, absent a manufacturer's deceptive commercial practices, have suffered an injury under General Business Law § 349. The Court, however, disagreed, holding that plaintiffs' definition of injury was legally flawed. *Id.*

In particular, the Court of Appeals held that plaintiffs' theory contained no manifestation of either pecuniary or "***actual***" harm, as required under the statute. Plaintiffs did not allege that the cost of cigarettes was affected by the alleged misrepresentation, nor did they seek recovery for ***injury to their health as a result of their ensuing addiction***. *Id. See also, Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, supra*, at 26, 623 N.Y.S.2d 529, 647 N.E.2d 741. Indeed, plaintiffs chose expressly to confine the relief sought solely to monetary recoupment of the purchase price of the cigarettes.

In rejecting plaintiffs' flawed "deception as injury" theory, the Court correctly pinpointed that addiction was inescapably the cornerstone of plaintiffs' legal claims. Because plaintiffs ***abandoned the injury to their health component*** of the legal theory of their case, i.e., addiction, they therefore failed to demonstrate that they were "actually harmed" by reason of any alleged deception within the meaning of the statute.

It is therefore abundantly clear that the "actual damages" component of §§ 349 & 350 of New York's General Business Law clearly encompasses claims for "injuries to health", i.e., personal injuries.

Lastly, Monsanto completely misrepresents the contents of Plaintiffs' complaint when alleging that Plaintiffs allege that they were injuriously exposed to glyphosate through ingestion of glyphosate residues on agricultural crops.

As a simple review of the Substantive Allegations section in Plaintiffs' Second Amended Complaint will reveal (paragraphs 86, 93-98), this section largely offers up a history of Roundup's usage, its approval process, its classification by the IARC, Monsanto's prior legal issues with the NYAG, and Roundup's general effects upon the public at large.

The Plaintiffs' actual allegations regarding their injuries are set forth in paragraphs 7 through 71 of the Second Amended Complaint. As the Court will discern from a review of these paragraphs, the Plaintiffs' do not allege therein that they were injuriously exposed to glyphosate through ingestion of glyphosate residues on agricultural crops.

PLAINTIFFS' NON-WARNING BASED STATE TORT LAW CLAIMS ARE NOT PREEMPTED

"Rules that require manufacturers to design reasonably safe products, to use due care in conducting appropriate testing of their products, to market products free of manufacturing defects," according to the *Bates* Court, "plainly do not qualify as requirements for 'labeling or packaging.'" 544 U.S. at 444. These common law rules do not require that manufacturers label or package their products in any particular way.

Therefore, Plaintiffs' claim for defective design are not preempted. *Id.*; *see also, Turner v. Chevron U.S.A. Inc.*, No. B173622, 2006 WL 1314013 (Cal. Ct. App. May 15, 2006) (design defect claims under the risk-benefit test because design defect claims "do not qualify as requirements for labeling or packaging") (citing *Bates*); *Wuebker v. Wilbur-Ellis Co.*, 418 F.3d 883, 886–87 (8th Cir. 2005).

CONCLUSION

For the foregoing reasons, the Plaintiffs respectfully request that the Court deny Monsanto's motion to dismiss.

Dated: Bronx, New York
February 12, 2016

Respectfully submitted,

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